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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,023	SEIBERG ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/26/04; 03/04/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are under examination.

Claims 16-57 are canceled by preliminary amendment.

Claim Rejections - 35 USC § 112

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrase "effective amount of a topically active composition" because active step does not clearly points out what is intended effect of "active" composition and what is treatment effective "active" agent. The claimed combination of phrases "effective" and "active" fails to point what is applied to the skin.

Claims 6 and 14 are rendered indefinite by recitation of "active" agent amounts such as 0% or 0 mg/ml. Claim has no meaning in the absence of at least some amounts of effective composition in the step of applying composition to the skin.

Claim 11 is indefinite and contains some empty space before phrase "mixture".

Regarding claim 15, the phrases "such as" and "the like" render the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 15 are rejected under 35 U.S.C. 102(b) as being DE 43 05 460 (IDS reference).

Claims are directed to a method for treating acne vulgaris and/or producing anti-aging effects on the surface of the skin comprising topically applying to the skin of a mammal an effective amount of a topically active composition with a first topically active agent. Some claims are further drawn to the first agent such as trypsin. Some claims are further drawn to the use of active agent in amounts up to 5% (w/v) or 0/01-1% (w/v). Some claims are further drawn to the use of vehicle and/or additional generic cosmetic ingredients.

DE 43 05 460 discloses a method for treating acne vulgaris and/or producing beneficial skin care effects (see English abstract) by topically applying to the skin of a mammal (see official translation page 11, lines 3-4) an effective amount of active agent or trypsin (abstract; translation page 7, lines 2-3) at concentration 0.1% - 33.3% (translation page 10, par. 2), a delivery vehicle or carrier and additional ingredients (page 10, par. 2-3). The cited patent teaches that the amount of carrier and active agent in composition is optimized with respect to skin and/or administration form (page 9, line 16; page 10, lines 1-3; page 11, lines 1-3).

Thus, the cited patent DE 43 05 460 anticipates that claimed method because it teaches identical step of applying to the skin identical composition with identical agent at identical amount for treating identical skin condition as required by the presently claimed method.

Claims 1-8 and 15 are rejected under 35 U.S.C. 102(b) as being US 5,665,366 (IDS reference).

Claims are directed to a method for treating acne vulgaris and/or producing anti-aging effects on the surface of the skin comprising topically applying to the skin of a mammal an effective amount of a topically active composition with a first topically active agent. Some claims are further drawn to the first agent such as trypsin. Some claims are further drawn to the use of active agent in amounts up to 5% (w/v) or 0/01-1% (w/v). Some claims are further drawn to the use of vehicle and/or additional generic cosmetic ingredients.

US 5,665,366 discloses a method for treating acne (abstract) and producing anti-aging effect through preventing dry flaky skin conditions and abnormal desquamation by facilitating desmosomal degradation (col.1, lines 5-10, col.11, lines 10-30) wherein the method comprises topically applying to the skin (col. 2, line 64) a composition with serine protease or trypsin or trypsin-like enzyme (col. 1, lines 62; col. 2, line 46), delivery vehicle in amount 10-99.9% (col. 3, line 43) and other ingredients such as surfactants, humecants, sunscreens, buffering agents, colorants, fragrances and etc.(col.5, lines 45-65). The patent also teaches concentration of serine protease 0.00001-50% (col. 2, line 14). The listing of pharmaceutically suitable proteases includes trypsin and subtilisin (col. 2, lines 40-46).

Thus, the cited patent US 5,665,366 anticipates that claimed method because it teaches identical step of applying identical composition with identical agent a identical amount for treating identical skin condition as required by the presently claimed method.

Claims 1-3, 8, 9 and 15 rejected under 35 U.S.C. 102(b) as being anticipated by US 5,834,290 (IDS reference).

Claims are directed to a method for treating acne vulgaris and/or producing anti-aging effects on the surface of the skin comprising topically applying to the skin of a mammal an effective amount of a topically active composition with a first topically active agent. Some claims are further drawn to the first agent such as serine protease. Some claims are further drawn to the use of vehicle or liposome and/or additional generic cosmetic ingredients.

US 5,834,290 discloses a method for treatment of various skin diseases including acne, (abstract, col. 23, line 14) and other skin conditions by applying to a skin of a mammal a composition with a topically active agent such as SCCE or serine protease (col. 20, lines 60-66) at concentration 1-80% (col. 21, line 12) in a pharmaceutical acceptable vehicle or liposome (col. 22, line 46) and other ingredients such as moisturizers, surfactants, humecants, buffering agents and etc. The composition is conventionally applied 1-10 times a day depending in the skin type and severity of conditions (col. 21, line 21).

Thus, the cited patent US 5,834,290 anticipates that claimed method because it teaches identical step of applying identical composition with identical agent a identical amount for treating identical skin condition as required by the presently claimed method.

Claims 1 and 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Niemiec et al. (Pharmaceutical Research. 1995. Vol. 12, No. 8, pages 1184-1188; IDS reference).

Claims are directed to a method for treating acne vulgaris and/or producing anti-aging effects on the surface of the skin comprising topically applying to the skin of a mammal an effective amount of a topically active composition with a first topically active agent. Some claims are further drawn to the use of first active agent or enzyme in zero amounts. Some claims

are further drawn to the use of vehicle or liposome comprising glycerol dilaurate, cholesterol and polyoxyethylene-10-stearyl ether in a ratio 53:10:22 to 63:20:32. Some claims are further drawn to the use of vehicle and/or additional generic cosmetic ingredients.

The reference by Niemiec et discloses a liposomal formulation which facilitates the topical delivery of peptide drugs (abstract) and which is comprised of glycerol dilaurate, cholesterol and polyoxyethylene-10-stearyl ether in a ratio 57:15:28 (p.1184 at last line). It also teaches that liposomes facilitate the topical delivery of peptide drugs deep into skin tissues or into pilosebaceous units or sebaceous glands.

Thus, the cited reference is considered to anticipate claims 1 and 8-15 because it comprises one identical active step of applying to the skin identical composition or identical liposome. Thus, practicing identical protocol is reasonably expected to result in the same effects.

With respect to claims 2-6, the cited reference is considered to anticipate the claimed method because the instant claims encompass the use of zero amount of active agent. The liposome of the cited reference does not contain active agent but the reference clearly teaches and suggests the liposome for delivery of peptide drug. The claimed enzymes that are required to be present in zero amount in the method of claims 2-6 are peptide drugs.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 4305460, US 5, 665, 366 and US 5, 834, 290 taken with Niemiec et al.

Claims are directed to a method for producing anti-acne vulgaris and anti-aging effects on the surface of the skin, comprising step of topically applying to the skin of a mammal a composition with an effective amount of topically active agent such as serine protease or trypsin, pharmaceutical vehicle such as liposome comprised of glycerol dilaurate, cholesterol and polyoxyethylene-10-stearyl ether in a ratio of about 53:10:22 to about 63:20:32 respectively and some other pharmaceutically or cosmetically suitable ingredients such as moisturizers, surfactants and etc..

The cited patents DE 4305460, US 5, 665, 366 and US 5, 834, 290 are relied upon as explained above for the disclosure of methods for treating skin conditions including anti-aging and/or anti-acne vulgaris effects by applying to a skin an effective amount of an active agent such as protease including serine protease and trypsin. They are lacking the disclosure of a particular pharmaceutically acceptable vehicle or liposome of defined composition in the method for skin care or treatment.

However, reference by Niemiec et al. discloses a liposomal formulation which facilitates the topical delivery of peptide drugs (abstract) and which is comprised of glycerol dilaurate, cholesterol and polyoxyethylene-10-stearyl ether in a ratio 57:15:28 (p.1184 at last line). It also teaches that liposomes facilitate the topical delivery of peptide drugs deep into skin tissues or into pilosebaceous units or sebaceous glands.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to invention to substitute the liposome of Niemiec et al. for

pharmaceutical vehicles in the composition with topically active agents for treating acne vulgaris and other skin-surface conditions of the cited patents DE 4305460, US 5,665,366 and/or US 5,834,290 in order to practice the method as claimed because liposomal formulations target and facilitate the topical delivery of peptide drugs as taught by Niemiec et al. and they are suitable for preparation with proteases as taught by US 5,834,290. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

March 18, 2005

V. Afremova

VERA AFREMOVA

PRIMARY EXAMINER